

REMARKS

A. Status of the Claims

Claims 1, 15, 29, 30, and 32 are amended without prejudice to more clearly claim the Applicants' invention. No new matter is added. Claims 1-32 are currently pending and presented for reconsideration.

B. Claim Rejection Under 35 U.S.C. §112, Second Paragraph

The Action maintains a rejection of claims 1 and 15 under 35 U.S.C. §112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention. The Action asserts that the claimed percentages of mean whole seed total oil content and mean whole seed total protein content do not add up correctly. Applicants traverse as stated in the previous response. However, in order to advance prosecution, claims 1, 15, 29, 30, and 32 are amended, and the rejection is believed to be moot. In view of the foregoing, withdrawal of the rejection is respectfully requested.

C. Claim Rejections Under 35 U.S.C. § 103(a)

The Action maintains the rejection of claims 1-32 as obvious over Wilcox (*Crop Sci.* 38:900, 1998) in view of Conway (U.S. Patent 6,140,556). Applicants respectfully traverse.

As an initial matter, pages 3-4 of the pending Action apparently assert that soybean line C1944 (= SN30003) is understood to be an agronomically elite soybean plant. Applicants traverse by noting that whether a soybean line is considered to be "agronomically elite" is not based solely on its yield potential, but rather on a combination of agronomic traits including, for instance, disease resistance, vigor, lodging resistance, and emergence among other traits, as well as yield, as discussed for instance in the Specification at page 13, line 10, and at page 38, lines 8-11. Thus, the Action's assertion that C1944 is "elite," apparently based only on its yield

potential, contradicts the teachings of the Specification and the definition of the term in the art, and is thus improper and without basis. Further, Wilcox 1998, cited as reference C43, does not describe C1944 as an agronomically elite variety, but instead as a breeding line, *i.e.* as germplasm for further breeding attempts.

The Action then asserts at page 4 that one of skill in the art would have had an expectation of success, in view of Wilcox (*Crop Sci.* 38:900, 1998, cited as C43) and Conway (U.S. 6,140,556), to produce novel soybean cultivars as claimed. Applicants respectfully submit that this assertion is **conclusory and mistaken**, in particular because no reference is discussed that would demonstrate that there would have been any expectation of success at the present filing date, in spite of the well-known negative correlation between the one or more of the traits of yield, mean whole seed total protein content, and mean whole seed total oil content, as discussed extensively in the Specification and in previous responses and which teaches away from such an expectation. That is, the Action provides no basis to support the assertion. Wilcox C43 clearly states that C1944 “...will be useful for...minimizing reduction in seed oil content.” (Wilcox, page 900, left column, end of 1st paragraph). Wilcox does not contemplate that the line will allow for producing elite soybean lines with the presently recited characteristics regarding both seed protein content and seed oil content. Conway teaches, unsurprisingly, that soybean plants may be crossed to produce novel soybean cultivars. Conway does not teach or suggest that it would be possible to obtain agronomically elite soybean plants displaying the claimed **protein and oil** content, especially given the negative correlation found among these traits.

Applicants also point to Wilcox 1998b (*Crop Sci.* 38:1536-1540, 1998; now cited as reference C83, not previously discussed on the record), which was discussed in the Interview of May 21, 2009. This reference notes, again, that when an increase in seed protein content is

selected for, then seed oil content declines (*i.e.* seed oil and seed protein content are negatively correlated: *e.g.* abstract; page 1536, left column; page 1537, right column, 1st paragraph of results and discussion; page 1539, right column, last full paragraph). These statements are fully in agreement with Applicants' previous arguments, and again show that there would have been **no expectation** in the art that the presently claimed **oil and protein content** could be achieved. This reference also notes that later cycles of recurrent selection displayed an even stronger inverse relationship between seed protein and oil content, as indicated by steeper slopes of and decreased variability around regression lines in later selection cycles (*See Abstract*). In particular, Applicants point to Fig. 3 at page 1538. This figure displays protein content vs. oil content for soybean lines undergoing multiple generations of recurrent selection for enhanced seed protein content. The inverse relationship between seed protein content and seed oil content is clearly evident in each plot.

In Fig. 3, top plot- the C0 generation, one breeding line outlier apparently displays a protein content of ~45% and an oil content of about 20.5%. However, this breeding line was apparently not selected for subsequent generations of breeding, or even if it was, its progeny did not maintain such levels of protein and oil. Applicants also note that yield and other agronomic characteristics that are also needed to determine whether any of these lines might be considered "elite" are not given; the lines that are being analyzed are clearly undergoing a breeding and selection process; and thus there is no basis to understand that these lines are "agronomically elite." Further, as discussed in the Specification, the expectation would be that the overall yield of a line displaying above average protein and oil content would be negatively impacted in view of the protein and oil content in its seed (*e.g.* see Wilcox *Crop Sci.* 35:1036-1041, 1995, previously cited, Figs. 1-2, and page 1040, right column). By the C8 generation also shown in

Fig. 3, no lines displaying ~45% protein displayed more than about 19% oil, while lines displaying ~48% protein had no more than about 18% oil, and typically less than ~17% oil. In sum, the Wilcox reference C83 agrees with the previously cited Wilcox 1998 reference C43, and further demonstrates the clear negative correlation between seed protein content and seed oil content, as well as the lack of any expectation of success that the presently claimed seed protein and oil content could be combined and maintained during a breeding process to achieve an agronomically elite soybean line displaying the recited protein, and oil levels.

The known negative correlation between seed protein and oil content teaches away from an expectation of success by itself. Additionally, when combined with the results described in references such as Wilcox C43 and C83 among others, a skilled worker **would not have expected that the claimed oil and protein levels could be achieved in an agronomically elite progeny plant** by the end of a breeding regime. Even if the outlier C0 generation plant of Fig. 3 of reference C83 is understood to display the presently claimed seed protein and oil contents, it is not an agronomically elite soybean plant, and the recited seed protein and oil levels were not displayed in any C4 or C8 generation plants. Thus, the recited seed protein and oil levels were not successfully maintained, or produced in an agronomically elite plant.

Further, the Wilcox references show that, in spite of possessing multiple lines which were used, **but by the present inventors**, (*i.e.* SN30003 = C1944 of C43), or **only in hindsight** might potentially have been used (C0 outlier line of Fig. 3 from a complex cross described at page 1536), to achieve the present invention, Wilcox simply did not proceed to achieve the claimed invention. This further demonstrates the non-obviousness of the invention from the standpoint of the skilled worker at the present filing date.

Applicants also traverse the assertion made on page 5 of the Action, that an oil content of “about 18.4%” would be understood in the art to include an oil content of “at least 20%”. That is, these ranges are non-overlapping and clearly distinct. Further, the present claims recite a combination protein and oil content, not oil content alone, and as noted above, these traits are negatively correlated. Thus, even if, only *in arguendo* and not conceded by Applicants, an individual C1944 plant displayed an oil content greater than 18.4%, Applicants respectfully submit that such a plant would be expected to display protein content of substantially less than the mean 48.8% protein content. The scatter plots of Fig. 3 of reference C83 illustrate this trend as well. For instance, in the C8 generation from that germplasm, a line displaying ~18.4% oil would display ~45-46% protein, but a line displaying ~20% oil would only display ~42-43% protein. Achieving both of the presently recited levels of seed protein and oil content in an agronomically elite cultivar is thus inventive, regardless of whether one or the other had been previously achieved in **separate** lines or cultivars. In view of the foregoing, withdrawal of the rejection is respectfully requested.

D. Claims Rejection Under 35 U.S.C. §102/103

The Action maintains the rejection of claims 1-12, 14, 15, 29, and 32 under 35 U.S.C. 102(b) as anticipated, or in the alternative, under 35 U.S.C. 103(a) as obvious over Wilcox (*Crop Sci.* 38:900, 1998). Applicants respectfully traverse.

As noted above in section “C,” whether a soybean line is considered to be “agronomically elite” is not based solely on its calculated yield level, but rather on a culmination of many agronomic traits including, for instance, emergence, disease resistance, vigor, and lodging resistance, among other traits, as well as yield, as discussed for instance in the

Specification at page 13, line 10, and at page 38, lines 8-11. Thus, the Action's assertion that C1944 is "elite," apparently based only on its yield potential, contradicts the teachings of the Specification and the definition of the term in the art, and is improper. Further, Wilcox 1998, cited as reference C43, does not describe C1944 as an agronomically elite variety, but instead as a breeding line, *i.e.* as germplasm for further breeding attempts. Thus, the Action's characterization of C1944 as an agronomically elite line is without basis.

Also, as noted in section "C" above, a mean seed oil content of "18.4%" is not equivalent to and would not encompass seed with at least 20% oil because: (1) these ranges are non-overlapping and distinct; (2) even if certain plants among the C1944 line displayed 20% seed oil (which is not conceded except *in arguendo*, is not discussed in the cited reference, and is apparently only hypothesized without basis in the Action), those same plants would clearly be expected to display substantially reduced protein content and/or reduced yield, given the known negative correlation between these traits. Applicants also point to the scatter plots of Fig. 3 of reference C83 again. Wherein at the C8 generation, presumably closest to being "agronomically elite," the lines displaying about 48% or more protein content, which is approximately what C1944 is described as displaying, displayed a range of about 15.5- 18% oil content, lines displaying about 45% protein content ranged from about 18-19% oil content, and the only lines displaying 20% or greater oil content showed only about 40-43% protein. Thus, again, there is no basis to expect that an individual C1944 plant, or an agronomically elite progeny plant of (((('Beeson' x 'Corsoy) x (Wells x Hark)) x (Cutler 71 x Pando))), from either of references C43 or C83, respectively, that might somehow display 20% mean whole seed oil content would also display 45% protein content, as described in the present Specification. Thus the rejection is without basis.

The Action also quotes Wilcox regarding “...increasing seed protein while **minimizing reductions in** seed oil content...” [emphasis added]. Applicants respectfully submit that this has been discussed previously, and it *prima facie* relates to minimizing a reduction in seed oil content, not to increasing seed oil content for instance to the level claimed (in combination with the recited seed protein content). Finally, the assertion that a skilled artisan would have had a reasonable expectation of success is made without basis, is tainted by hindsight reasoning, and is taught away-from in the art, as discussed above and in previous responses. On the contrary, the three references by Wilcox that are discussed above (*Crop Sci.* 38:900, 1998; *Crop Sci* 38:1536-1540, 1998; *Crop Sci* 35:1036-1041, 1995), as well as other references previously discussed, individually and cumulatively demonstrate that seed oil content and seed protein content are negatively correlated when paired and that if yield is added as a third selection parameter, at best only two of the three parameters would be expected to be maintained in a breeding program. In spite of developing C1944, Wilcox did not apparently pursue or achieve the present invention, nor has anyone else since development of C1944 was published more than 10 years ago. Applicants respectfully submit that this is also *prima facie* evidence regarding the non-obviousness of the invention. Withdrawal of the rejection is therefore respectfully requested.

E. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (214) 259-0932 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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